

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant(s) : MacLaughlin et al.  
U.S. Serial No. : To Be Assigned  
Filing Date : Herewith  
For : DELIVERY OF THERAPEUTIC BIOLOGICALS  
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**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

The Examiner's attention is respectfully drawn to the enclosed documents listed on the accompanying PTO form 1449. Copies of the documents were previously submitted with Information Disclosure Statements filed November 6, 2001, April 5, 2002, December 17, 2002, and March 7, 2003 directed to related application Serial No. 09/770,339 filed on January 26, 2001. Accordingly, no copies are submitted herewith.

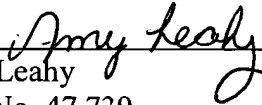
As this Information Disclosure Statement is being filed before the mailing of the first Office Action, it is believed that no fee is required for entry of this paper. However, the Commissioner is hereby authorized to charge any such fee, or credit any overpayment to Deposit Account 50-0320.

The filing of this Information Disclosure Statement is not an admission that the documents identified herein constitute prior art to the present application.

Applicants respectfully request that the Examiner considers and makes of record the documents cited herewith and that a copy of Form PTO-1449 be initialed by the Examiner and returned to the undersigned.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP  
Attorneys for Applicants

  
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Encs. PTO form 1449  
References (60)

Based on Form PTO-1449 (3/90)				ATTY. DOCKET NO.  <b>910000-2019.1</b>		SERIAL NO.  <b>To Be Assigned</b>		
LIST OF REFERENCES CITED BY APPLICANT (Use several sheets if necessary)				APPLICANT  <b>MacLaughlin et al.</b>				
				FILING DATE  <b>Herewith</b>		GROUP  <b>To Be Assigned</b>		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	U.S. 4,404,199	09/13/83	Bonaldi et al.				
	AB	U.S. 4,487,833	12/11/84	Donahoe et al.				
	AC	U.S. 4,510,131	04/09/85	Donahoe et al.				
	AD	U.S. 4,753,794	06/28/88	Donahoe				
	AE	U.S. 4,792,601	12/20/88	Donahoe et al.				
	AF	U.S. 5,011,687	04/30/91	Donahoe et al.				
	AG	U.S. 5,047,336	09/10/91	Cate et al.				
	AH	U.S. 5,198,420	03/30/93	Donahoe et al.				
	AI	U.S. 5,204,055	04/20/93	Sachs et al.				
	AJ	U.S. 5,661,126	08/26/97	Donahoe et al.				
	AK	U.S. 5,709,854	01/20/98	Griffith-Cima et al.				
FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AL	WO 93/17669	09/16/93	WIPO				
	AM	WO 94/25080	11/10/94	WIPO				
	AN	WO 96/40002	12/19/96	WIPO				
	AO	WO 94/00133	01/06/94	WIPO				
	AP							
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)								
	AQ		Amalfitano and Parks, "Separating Fact from Fiction: Assessing the Potential of Modified Adenovirus Vectors for Use in Human Gene Therapy", Current Gene Therapy, 2002, 2, 111-133					
	AR		Bogden, et al., "Growth of human tumor xenografts implanted under the renal capsule of normal immunocompetent mice," Exp Cell Biol 47(4): 281-93 (1979)					
	AS		Boveri, et al., "Transfection of the Mullerian inhibiting substance gene inhibits local and metastatic tumor growth," Int J. Oncology 2: 135-44 (1993)					
	AT		Budzik, et al., "Mullerian inhibiting substance fractionation by dye affinity chromatography," Cell 34: 307-314 (1983)					
	AU		Cao et al., "Expression of angiostatin cDNA in a murine fibrosarcoma suppresses primary tumor growth and produces long-term dormancy of metastases" J. Clin. Invest., vol. 101, no. 5, 5 March 1998, pgs 1055-1063					
	AV		Cate, et al., "Development of Mullerian inhibiting substance as an anti-cancer drug," Cold Spring Harbor Symp Quant Biol 51(Pt 1): 641-7 (1986)					
EXAMINER				DATE CONSIDERED				
* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AW	U.S. 5,759,830	06/02/98	Vacanti et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES      NO
	AX						
OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
	AY		Cate, et al., "Isolation of the bovine and human genes for Mullerian inhibiting substance and expression of the human gene in animal cells," Cell 45: 685-98 (1986)				
	AZ		Chamberlain, et al., "Early peripheral nerve healing in collagen and silicone tube implants: myofibroblasts and the cellular response," Biomaterials 19(15): 1393-1403 (1998)				
	BA		Chin, et al., "Human mullerian inhibiting substance inhibits tumor growth in vitro and in vivo," Cancer Research 51: 2101-2106 (1991)				
	BB		Donahoe, et al., "A graded organ culture assay for the detection of Mullerian inhibiting substance," J Surg Res 23: 141-8 (1977)				
	BC		Donahoe, et al., "Mullerian duct regression in the embryo correlated with cytotoxic activity against human ovarian cancer," Science 205: 913-5 (1979)				
	BD		Donahoe, et al., "Mullerian inhibiting substance inhibits growth of a human ovarian cancer in nude mice," Ann Surgery 194: 472-80 (1981)				
	BE		Fingert, et al., "Rapid growth of human cancer cells in a mouse model with fibrin clot subrenal capsule assay," Cancer Res. 47: 3824-3829 (1987)				
	BF		Fuller, et al., "Mullerian inhibiting substance inhibits colony growth of a human ovarian carcinoma cell line," J Clin Endocr Metab. 54: 1051-5 (1982)				
	BG		Fuller, et al., "Mullerian inhibiting substance reduction of colony growth of human gynecologic cancers in a stem cell assay," Gynecol. Oncol. 22: 135-148 (1985)				
	BH		Gilbert et al., "Cell transportation of genetically altered cells on biodegradable polymer scaffolds in syngeneic rats," Transplantation, vol. 56, 2 August 1998, pgs 423-427				
	BI		Gustafson, et al., "Mullerian inhibiting substance as a marker for ovarian sex-cord tumor," N. Eng. J. Med. 326(7): 466-471 (1992)				
	BJ		Hadlock, et al., "A novel, biodegradable polymer conduit delivers neurotrophins and promotes nerve regeneration," Laryngoscope 109(9): 1412-1416 (1999)				
	BK		Hudson, et al., "An immunoassay to detect human mullerian inhibiting substance in males and females during normal development," J Clin Endocrinol Metab. 70:16-22 (1990)				
	BL		Krist Jansen, et al., "Tissue-isolated human tumor xenografts in athymic nude mice," Microvasc. Res. 48: 389-402 (1994)				
	BM		Kurian, et al., "Cleavage of Mullerian inhibiting substance activates antiproliferative effects in vivo," Clin. Cancer Res. 1(3): 343-349 (1995)				
	BN		Lee, et al., "Mullerian inhibiting substance in humans: normal levels from infancy to adulthood," J Clin Endocrinol Metab. 81: 571-69 (1996)				
	BO		Li and Ma, "Nonviral Gene Therapy," Current Gene Therapy, 2001, 1, 201-226				
	BP		Lorenzo et al., "New Approaches for High-Yield Purification of Mullerian Inhibiting Substance Improve Its Bioactivity" Journal of Chromatography B: Analytical Technologies in the Biomedical and Life Sciences, vol. 766, Issue 1, pgs 89-98 (2002)				
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U.S. PATENT DOCUMENTS							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	BQ						

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES      NO
	BR						

OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)		
BS		MacLaughlin, et al., "Bioassay, purification, cloning and expression of Mullerian inhibiting substance," Methods Enzymol. 198: 358-69 (1991)
BT		MacLaughlin, et al., "Mullerian duct regression and antiproliferative bioactivities of mullerian inhibiting substance reside in its carboxy-terminal domain," Endocrinology 131(1): 291-6 (1992)
BU		Masiakos, et al., "Human ovarian cancer, cell lines, and primary ascites cells express the human Mullerian inhibiting substance (MIS) type II receptor, bind, and are responsive to MIS," Clinical Cancer Research 5(11): 3488-99 (1999)
BV		Matsuda, et al., "Photoinduced prevention of tissue adhesion," ASAIO Trans. 38: 154-157 (1992)
BW		O'Reilly, et al., "Antiangiogenic activity o the cleaved conformation of the serpin antithrombin," Science 285(5435): 1926-8 (1999)
BX		Parry, et al., "Recombinant human mullerian inhibiting substance inhibits human ocular melanoma cell lines in vitro and in vivo," Cancer Res. 52: 1182-6 (1992)
BY		Pepinsky, et al., "Proteolytic processing of mullerian inhibiting substance produces a transforming growth factor-beta-like fragment," J. Biol. Chem. 263: 18961-41 (1988)
BZ		Qin et al., "Interferon-beta gene therapy inhibits tumor formation and causes regression of established tumors in immune-deficient mice," Proc. Natl. Acad. Sci. USA, vol. 95, November 1998, pgs 14411-14416
CA		Ragin, et al., "Human mullerian inhibiting substance: enhanced purification imparts biochemical stability and restores antiproliferative effects," Protein Expression and Purification 3(3): 236-45 (1992)
CB		Segev et al., "Mullerian Inhibiting Substance Inhibits Breast Cancer Cell Growth through an NFkB-mediated Pathway" Journal of Biological Chemistry," vol. 275(37), Issue of September 15, pgs. 28371-28379 (2000)
CC		Segev et al., "Mullerian Inhibiting Substance Regulates NFkB Signalling and Growth of Mammary Epithelial Cells in Vitro," Journal of Biological Chemistry, vol. 276(29), Issue of July 20, pgs. 26799-26806 (2001)
CD		Segev et al., "Mullerian-inhibiting substance regulates NF-kB signalling in the prostate in vitro and in vivo" PNAS, vol. 99(1), pgs 239-244 (2002)
CE		Stephen et al., "Highly Purified Mullerian Inhibiting Substance Inhibits Human Ovarian cancer in Vivo" Clinical Cancer Research, vol. 8, pgs 2640-2646 (2002)
CF		Stephen et al., "Tissue-engineered cells producing complex recombinant proteins inhibit ovarian cancer in vivo" Proc. Natl. Acad. Sci. USA, vol. 98, no. 6, 13 March 2001, pgs 3214-3219
CG		Teixeira, et al., "Molecular biology of MIS and its receptors," Androl. 17(4): 336-41 (1996)

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